PCT/CA 2004/000064
30 MARCH 2004 30-03-04

PA 1136227

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APPLICATION NUMBER: ***60/518,345***
FILING DATE: ***November 10, 2003***

PCT/CA04/00064

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
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FEE RECORD SHEET

11/13/2003 DTESSEM1 00000037 022095 60518345
01 FC:1005 160.00 DA

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-267/69033

PTO/SB/16 (08-0 .)
Approved for use through 07/31/2008, OMB 0651-00X.
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERC

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

PHARMACEUTICAL DELIVERY SYSTEMS AND METHODS FOR USING SAME

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 27 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 17 ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

FILING FEE AMOUNT ($)

☒ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 022095 — 160.00

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____.

[Page 1 of 1]

Respectfully submitted.
SIGNATURE _____

Date November 10, 2003

TYPED or PRINTED NAME Andrew I. McIntosh

REGISTRATION NO. *(if appropriate)* 40,453

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Docket Number: 12916-62

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to proce-) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, a.d submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete t is form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. B ox 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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B&P File No. 12916-62

BERESKIN & PARR **UNITED STATES**

Title: **Pharmaceutical Delivery Systems and Methods for Using Same**

Inventor: **David L. Reynolds**

PHARMACEUTICAL DELIVERY SYSTEMS AND METHODS FOR USING SAME

FIELD OF THE INVENTION

[0001] The present invention generally relates to pharmaceutical delivery systems, and to methods for using same. More specifically, it relates to an assembly for transferring one or more components of a pharmaceutical composition from a pharmaceutical vial to a syringe or vice versa.

BACKGROUND OF THE INVENTION

[0002] Traditionally, a syringe is filled manually by aspirating a liquid pharmaceutical component from a pharmaceutical vial having a neck with a penetrable closure into the syringe through a needle that penetrates the penetrable closure. The method of manually filling the syringe typically includes the following steps: (a) drawing air into the body of the syringe by pulling the syringe's plunger away from the needle end of the syringe until the volume of air in the body approximately equals the volume of pharmaceutical component to be loaded into the syringe; (b) carefully aligning the needle with the vial's penetrable closure and inserting the needle through the penetrable closure into the vial; (c) inverting the vial and forcing the air from the body of the syringe into the vial by advancing the syringe's plunger; (d) withdrawing the plunger to draw out the desired volume of the pharmaceutical component into the syringe; and (e) removing the needle from the vial.

[0003] This method suffers from various disadvantages. Firstly, the user is exposed to the unprotected needle tip, which can result in accidental stabbings or prickings. Secondly, if the user wishes to draw a large volume of the pharmaceutical component into the syringe (e.g., 10 cc) an equivalent volume of air must be forced into the vial. This can increase the pressure in the pharmaceutical vial to the point where the pharmaceutical component may spray through the puncture point made by the needle in the penetrable seal and onto the user. These accidents can be particularly dangerous if the pharmaceutical component is unsafe to the user, for example with toxic oncology pharmaceuticals. Thirdly, the sterility of the needle may be

compromised during the process of transferring the pharmaceutical component from the vial to the syringe.

[0004] Additionally, many pharmaceutical preparations must be distributed as two or more separate components (commonly a solid component and a liquid component in which the solid component should be reconstituted shortly before administration of the preparation although it could be two liquid components). Traditionally, this reconstitution includes the following steps: (a) providing a first component packaged in a pharmaceutical vial having a neck closed by a penetrable closure; (b) providing a second liquid component in a syringe; (c) injecting the second liquid component into the vial through the penetrable closure; (d) swilling the vial impaled on the syringe to dissolve, dilute or suspend the first component in the second component; and (e) aspirating the combined components back into the syringe. Alternatively, the two or more components may be liquid and require mixing just prior to administration. The mixing may be accomplished in an analogous manner. These methods suffer from many of the disadvantages described above.

[0005] There is a need for a pharmaceutical delivery system that can be used with standard pharmaceutical vials and syringes, which enhances safety and ease of manipulation, and is economical to manufacture.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] For a better understanding of the present invention and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings which illustrate various embodiments of the invention and in which:

[0007] Figure 1 is an exploded side elevational view of a pharmaceutical delivery system including a pharmaceutical transfer assembly according to one aspect of the present invention;

[0008] Figures 2-7 illustrate successive stages in the deployment of the pharmaceutical transfer assembly as shown in Figure 1 to reconstitute a multi-component pharmaceutical according to a further aspect of the invention;

[0009] Figures 8-13 illustrate successive stages in the deployment of the pharmaceutical transfer assembly as shown in Figure 1 to reconstitute a multi-component pharmaceutical according to a further aspect of the invention;

[0010] Figures 14-19 illustrate successive stages in deployment of the pharmaceutical transfer assembly as shown in Figure 1 to transfer a fluid pharmaceutical component from a prepackaged pharmaceutical vial to a syringe according to a further aspect of the invention;

[0011] Figure 20 is an exploded side elevational view of a pharmaceutical delivery system including a pharmaceutical transfer assembly according to a further aspect of the present invention;

[0012] Figures 21-26 illustrate successive stages in the deployment of the pharmaceutical transfer assembly of Figure 20 to transfer a fluid pharmaceutical component from a prepackaged pharmaceutical vial to a syringe according to a further aspect of the invention;

[0013] Figure 27 is an exploded cross-sectional view of a pharmaceutical delivery system including a pharmaceutical transfer assembly according to a further aspect of the present invention;

[0014] Figure 28 is an exploded side elevational view of the pharmaceutical delivery system of Figure 27;

[0015] Figure 29 is a cross-sectional view of the pharmaceutical transfer assembly of Figure 27 attached to a syringe with a needle hub assembly in a retracted position relative to a housing and a transfer needle plunger rod in a first position relative to a backstop;

[0016] Figure 30 is a cross-sectional view of the pharmaceutical transfer assembly of Figure 27 attached to both a syringe and a vial with a

needle hub assembly in a retracted position relative to a housing and a transfer needle plunger rod in a second position relative to a backstop;

[0017] Figure 31 is a cross-sectional view of the pharmaceutical transfer assembly of Figure 27 attached to a syringe and a vial with a needle hub assembly in an advanced position relative to a housing and a transfer needle plunger rod in a second position relative to a backstop;

[0018] Figures 32-37 illustrate successive stages in the deployment of the pharmaceutical transfer assembly of Figure 27 to reconstitute a multi-component pharmaceutical according to a further aspect of the present invention;

[0019] Figure 38 is an exploded cross-sectional view of a syringe according to a further aspect of the present invention;

[0020] Figure 39 is a cross-sectional view of the syringe of Figure 39 in a first position;

[0021] Figure 40 is a cross-sectional view of the syringe of Figure 39 in a second position; and

[0022] Figure 41 is a perspective view of a backstop according to a one aspect of the present invention; and

[0023] Figure 42 is a perspective view of a backstop according to a further aspect of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0024] The pharmaceutical transfer assemblies described herein are adapted to be used with a standard pharmaceutical vial and a standard syringe or slightly modified versions thereof. These standard devices are well known in the art, but examples will be described here briefly.

[0025] As best seen in Figure 1, a standard pharmaceutical vial 10 generally has a vial body 12, a neck 14 of a reduced diameter compared with the body 12, a penetrable closure 16 made of an elastomeric material (e.g. rubber), a cap 18 to hold the penetrable closure 16 onto the pharmaceutical

vial 10, and a cover 20 to protect the integrity of the penetrable closure 16 before use.

[0026] Still referring to Figure 1, a standard syringe 22 may be a mass-produced moulded plastic syringe having a syringe body 24 being open at one end 26 and having a neck 28 at the opposite end. A piston 30 is lodged in the the syringe body 24 from the open end 26, the piston 30 being provided with means (not shown) by which a standard detachable plunger rod (not shown) may be secured to the piston 30. The open end 26 of the syringe body 24 is provided with a flange 27. The neck 28 of the syringe body 24 has a standard needle coupling or "luer lock" comprising a conical spigot (not shown) with a central passage communicating with the syringe body 24 surrounded by a cylindrical sleeve (not shown) having an internal thread (not shown). The neck 28 of the syringe body 24 is sealed with a tip cap 32 made of a elastomeric material (e.g. rubber).

[0027] Still referring to Figure 1, a pharmaceutical delivery system made in accordance with one aspect of the present invention is shown generally at 34. The pharmaceutical delivery system 34 generally comprises the syringe 22 pre-filled with a first fluid pharmaceutical component, a pharmaceutical transfer assembly shown generally at 36, and the pharmaceutical vial 10 containing a second pharmaceutical component. It is understood that the second pharmaceutical component may be either a fluid or a solid (e.g. lyophilized powder). The pharmaceutical transfer assembly 36 generally comprises a detachable needle transfer plunger rod shown generally at 38, and a vial socket assembly shown generally at 40.

[0028] The detachable needle transfer plunger rod 38 may be of any suitable size and shape. In one aspect of the invention, the detachable needle transfer plunger rod 38 has the same dimensions as a standard detachable plunger rod as is well known by a person skilled in the syringe art. The detachable needle transfer plunger rod 38 generally comprises a housing 42, a needle hub assembly 44, and a resilient biasing member 46.

[0029] The housing 42 has a first open end 48, a second open end 50 opposite open end 48, and an inner sleeve 52 disposed between the first and second open ends 48, 50. The inner sleeve 52 is appropriately sized and shaped to receive the needle hub assembly 44 and the resilient biasing member 46, which will be described in more detail below. The inner sleeve 52 generally has a first portion 54 and an adjacent second portion 56. The first portion 54 has a larger diameter than the second portion 56, and an inner annular shoulder 58 is formed at the juncture between the first and second portions 54, 56. There is an annular detent 60 in the first portion 54 to provide a snap fit connection to secure the needle hub assembly 44 in a retracted or "inactivated" position while not in use, as will be subsequently described. There is an internal thread 62 in the first portion 54 of the inner sleeve 52 that cooperates with an external thread 64 on the vial socket assembly 40 to securely lock the vial socket assembly 40 onto the needle transfer plunger rod 38 thereby advancing the needle hub assembly 44 into an advanced or "activated" position, as will be subsequently described. There is an external thread 66 on the second open end 50 of the housing 42 that cooperates with an internal thread (not shown) contained within the piston 30 to permit the needle transfer plunger rod 38 to be coupled to the syringe 22. The first open end 48 of the housing 42 preferably has a finger flange 68 with a central bore (not shown) to aid in gripping the pharmaceutical transfer assembly 36 during operation.

[0030] The needle hub assembly 44 generally comprises a first hollow piercing member 70 having a tip 72 coupled to a needle hub 74. The first hollow piercing member 70 may be any suitable device well known in the art, and in one embodiment is a hollow needle such as a standard cannula. The needle hub assembly 44 is adapted for longitudinal movement within the inner sleeve 52 between a retracted or "unactivated" position (as seen in Figures 2-3, 7, 8-9, 12, 14-15, 19) and an advanced or "activated" position (as seen in Figures 4-6, 10-12, 16-18). As will be described more particularly below, in the retracted position, the tip 72 of the first hollow piercing member 70 is fully contained within the second portion 56 of the inner sleeve 52 of the housing

42. In the advanced position, the tip 72 of the first hollow piercing member 70 protrudes past the second portion 56 of the inner sleeve 52 of the housing 42 and penetrates the piston 30. The needle hub 74 has a female luer slip fitting to permit receipt of a post 76 of the vial socket assembly 40. The needle hub 74 and the post 76 act to hold the vial socket assembly 40 to the needle transfer plunger rod 38 initially when the needle hub assembly 44 is in the retracted or "inactivated" position.

[0031] The resilient biasing member 46 may be any suitable device well known in the art, and in one embodiment is a compressible spring. The resilient biasing member 46 is adapted to fit within the first portion 54 of the inner sleeve 52 between the surface of the needle hub 74 and the annular shoulder 58. While the needle hub assembly 44 is in the retracted or "unactivated" position, the resilient biasing member 46 is at rest (e.g. no force is being applied to or by the resilient biasing member 46 by the hub 74). While the needle hub assembly 44 is in the advanced or "activated" position, the resilient biasing member 46 is compressed against the annular shoulder 58 by the hub 74 (e.g., a force is being applied to the resilient biasing member 46). The main purpose of the resilient biasing member 46 is to retract the needle hub assembly 44 back to the original retracted or "unactivated" position after the fluid transfer has been completed and the vial socket assembly 40 has been removed from the needle transfer plunger rod 38, as will subsequently be described.

[0032] The vial socket assembly 40 generally comprises the post 76, a second hollow piercing member 78 having a tip 80, and a vial socket 82. The post 76 has a male luer slip fitting that permits coupling between the post 76 and the needle hub 74 while the pharmaceutical transfer assembly is in the retracted or "inactivated position". The second hollow piercing member 78 may be any suitable device well known in the art, and in one embodiment is a hollow needle such as a standard spike. The vial socket 82 is appropriately sized and shaped to receive a standard pharmaceutical vial 10 having the penetrable closure 16 and the cap 18, described above. Preferably, the vial

socket 82 has an inner annular ridge 84 of smaller dimension than the vial socket 82 for positively engaging the cap 18 of the vial 10 once it is fully inserted into the vial socket 82 (as shown in Figures 2-3, 8-9, and 14-15).

[0033] Referring now to Figures 2-7, the successive stages in the deployment of a pharmaceutical transfer assembly 36 as shown in Figure 1 to reconstitute a first fluid pharmaceutical component from a pre-filled syringe 22 with a second pharmaceutical component from a pharmaceutical vial 10 are shown. It is understood that the second pharmaceutical component contained within the pharmaceutical vial 10 may be either a fluid or a solid (e.g. lyophilized powder).

[0034] Still referring to Figures 2-7, the method for deploying the pharmaceutical transfer assembly 36 is described in detail below. Step (a) involves screwing external thread 66 into the internal thread (not shown) within piston 30 and inserting the post 76 of the vial socket assembly 40 into the needle hub 74 to create the assembly shown in Figure 2. Step (b) involves removing the cover 20 of the pharmaceutical vial 10 (see Figure 3). Step (c) involves inserting and snap fitting the pharmaceutical vial 10 into the vial socket 82 of the vial socket assembly 40 such that the tip 80 of the second hollow piercing member 78 penetrates the penetrable closure 16 on the pharmaceutical vial 10 (see Figure 3). It is understood that the two procedures of step (a) can be performed first followed by steps (b) and (c) in that order, or steps (b) and (c) can be performed first in that order followed by step (a). After completing steps (a), (b), and (c), step (d) involves advancing both the pharmaceutical vial 10 and the vial socket assembly 40 forward towards the syringe 22 and locking the vial socket assembly 40 into place by screwing the external thread 64 into the internal thread 62 of the plunger rod housing 42. This, in turn, advances the tip 72 of the first hollow piercing member longitudinally within the inner sleeve 52 of the housing 42 from the retracted position to the advanced position wherein the tip 72 of the first hollow piercing member 70 penetrates the piston 30. With both tip 72 and tip 80 having pierced their respective items, this creates fluid communication

between the pharmaceutical vial 10 and the syringe 22 (see Figure 4). Step (e) involves advancing the syringe body 24 longitudinally towards the pharmaceutical vial 10. This moves piston 30 relative to neck 28 to force the fluid within the syringe body 24 into and through the needle assembly 44 and through the vial socket assembly 40 to inject the first fluid pharmaceutical component into the pharmaceutical vial 10 (see Figure 5). Step (f) involves swirling the pharmaceutical delivery system 34 to dissolve, dilute or suspend the first fluid pharmaceutical component into the second pharmaceutical component. Step (g) involves inverting the pharmaceutical delivery system 34 and withdrawing the syringe body 24 longitudinally away from the pharmaceutical vial 10 to aspirate the now mixed contents of the pharmaceutical vial 10 back into the syringe 22 (see Figure 6). Step (h) involves detaching the vial socket assembly 40 from the needle transfer plunger rod 38 (by unthreading the two and pulling the post 76 of the vial socket assembly 40 out of the needle hub 74) to provide a filled syringe 22 ready for use (see Figure 7). To use the filled syringe the tip cap 32 is removed and a needle (not shown) attached. The needle transfer plunger rod 38 forms the plunger to discharge the mixed pharmaceutical from the syringe 22.

[0035] It is understood by a person skilled in the art that once the vial socket assembly 40 is detached from the needle transfer plunger rod (by unthreading the two), the resilient biasing member 46 retracts the first hollow piercing member back to the retracted or "inactivated" position. As such, the piston 30 reseals to prevent fluid communication between the syringe 22 and the needle transfer plunger rod 38. Accordingly, when the syringe 22 is used to deliver the reconstituted multi-component pharmaceutical to a patient or iv line, the needle transfer plunger rod 38 is depressed in a conventional way.

[0036] Referring now to Figures 8-13, the successive stages in the deployment of a pharmaceutical transfer assembly 36 as shown in Figure 1 to reconstitute a first pharmaceutical component from a prepackaged syringe 22 with a second fluid pharmaceutical component from a prepackaged

pharmaceutical vial 10 are shown. It is understood that the first pharmaceutical component contained within the syringe 22 may be either a fluid or a solid (e.g., lyophilized powder).

[0037] Still referring to Figures 8-13, the method for deploying the pharmaceutical transfer assembly 36 is described in detail below. Step (a) involves screwing external thread 66 into the internal thread (not shown) within piston 30 and inserting post 76 of the vial socket assembly 40 into the needle hub 74 to create the assembly shown in Figure 8. Step (b) involves removing the cover 20 of the pharmaceutical vial 10 (Figure 9). Step (c) involves inserting and snap fitting the pharmaceutical vial 10 into the vial socket 82 of the vial socket assembly 40 such that the tip 80 of the second hollow piercing member 78 penetrates the penetrable closure 16 on the pharmaceutical vial 10 (see Figure 9). It is understood that the two procedures of step (a) can be performed first followed by steps (b) and (c) in that order, or steps (b) and (c) can be performed first in that order followed by step (a). After completing steps (a), (b), and (c), step (d) involves advancing both the pharmaceutical vial 10 and the vial socket assembly 40 forward towards the syringe 22 and locking the vial socket assembly 40 into place by screwing the external thread 64 into the internal thread 62 of the plunger rod housing 42. This, in turn, advances the tip 72 of the first hollow piercing member 70 longitudinally within the inner sleeve 52 of the housing 42 from the retracted position to the advanced position wherein the tip 72 of the first hollow piercing member 70 penetrates the piston 30. With both tip 72 and tip 80 having pierced their respective items, this creates fluid communication between the pharmaceutical vial 10 and the syringe 22 (see Figure 10). Step (e) involves inverting the pharmaceutical delivery system 30 and advancing the syringe body 22 longitudinally towards the pharmaceutical vial 10. This moves piston 30 relative to neck 28 to force the air within the syringe body 24 into and through the needle assembly 44 and through the vial socket assembly 40 to aspirate the air into the pharmaceutical vial 10. Step (f) involves withdrawing the syringe body 24 away from the pharmaceutical vial to aspirate the second, fluid pharmaceutical from the pharmaceutical vial 10

into the syringe 22 (see Figure 11). Step (g) involves swirling the pharmaceutical delivery system 34 to dissolve, dilute or suspend the second, fluid pharmaceutical component into the first pharmaceutical component. Step (h) involves detaching the vial socket assembly 40 from the needle transfer plunger rod 38 (by unthreading the two and pulling the post 76 of the vial socket assembly 40 out of the needle hub 74) to provide a filled syringe 22 ready for use (see Figure 13). To use the filled syringe the tip cap 32 is removed and a needle (not shown) attached. The needle transfer plunger rod 38 forms the plunger to discharge the mixed pharmaceutical from the syringe 22.

[0038] Referring now to Figures 14–19, the successive stages in deployment of the pharmaceutical transfer assembly 36 as shown in Figure 1 to transfer a fluid pharmaceutical component from a prepackaged pharmaceutical vial 10 to an empty syringe 22 according to a further aspect of the invention are shown.

[0039] Still referring to Figures 14-19, the method for deploying the pharmaceutical transfer assembly 36 is described in detail below. Step (a) involves screwing external thread 66 into the internal thread (not shown) within piston 30 and inserting post 76 of the vial socket assembly 40 into the needle hub 74 to create the assembly shown in Figure 14. Step (b) involves removing the cover 20 of the pharmaceutical vial 10 (Figure 15). Step (c) involves inserting and snap fitting the pharmaceutical vial 10 into the vial socket 82 of the vial socket assembly 40 such that the tip 80 of the second hollow piercing member 78 penetrates the penetrable closure 16 on the pharmaceutical vial 10 (see Figure 15). It is understood that the two procedures of step (a) can be performed first followed by steps (b) and (c) in that order, or steps (b) and (c) can be performed first in that order followed by step (a). After completing steps (a), (b), and (c), step (d) involves advancing both the pharmaceutical vial 10 and the vial socket assembly 40 forward towards the syringe 22 and locking the vial socket assembly 40 into place by screwing the external thread 64 into the internal thread 62 of the plunger rod

housing 42. This, in turn, advances the tip 72 of the first hollow piercing member 70 longitudinally within the inner sleeve 52 of the housing 42 from the retracted position to the advanced position wherein the tip 72 of the first hollow piercing member 70 penetrates the piston 30. With both tip 72 and tip 80 having pierced their respective items, this creates fluid communication between the pharmaceutical vial 10 and the syringe 22 (see Figure 16). Step (e) involves advancing the syringe body 24 longitudinally towards the pharmaceutical vial 10 to aspirate air into the pharmaceutical vial 10. Step (f) involves inverting the pharmaceutical delivery system 34 to aspirate the fluid pharmaceutical component from the prepackaged pharmaceutical vial 10 into the syringe 22. Step (g) involves detaching the vial socket assembly 40 from the needle transfer plunger rod 38 (by unthreading the two and pulling the post 76 of the vial socket assembly 40 out of the needle hub 74) to provide a syringe 22 ready for use (see Figure 19). To use the filled syringe the tip cap 32 is removed and a needle (not shown) attached. The needle transfer plunger rod 38 forms the plunger to discharge the transferred fluid from the syringe 22.

[0040] Referring now to Figure 20, a pharmaceutical delivery system made in accordance with another aspect of the present invention is shown generally at 134. The pharmaceutical delivery system 134 generally comprises an empty syringe 122, a pharmaceutical transfer assembly shown generally at 136, and a pharmaceutical vial 110 containing a fluid pharmaceutical component. The pharmaceutical transfer assembly 136 generally comprises a detachable plunger rod shown generally at 138, and a transfer tube / vial socket assembly shown generally at 139.

[0041] The detachable plunger rod 138 may be of any suitable size and shape. In one aspect of the invention, the detachable plunger rod 138 has the same dimensions as a standard detachable plunger rod as is well known by a person skilled in the syringe art.

[0042] The detachable plunger rod generally comprises a housing 142. The housing 142 has a first open end 148, a second open end 150 opposite

the first open end 148, and an inner sleeve 152 disposed between the first and second open ends 148, 150. The inner sleeve 152 is appropriately sized and shaped to receive the transfer tube / vial socket assembly 139, which will be described in more detail below. The inner sleeve 152 generally has a first portion 154, and an adjacent second portion 156. The first portion 154 has a larger diameter than the second portion 156. There is an internal thread 162 in the first portion 154 of the inner sleeve 152 that cooperates with an external thread 164 on the transfer tube / vial socket assembly 139 to couple the plunger rod 138 to the transfer tube / vial socket assembly 139. These cooperating threads 162, 164 permit axial movement of the transfer tube / vial socket assembly 139 relative to the plunger rod 138. There is an external thread 166 on the second open end 150 of the housing 142 that cooperates with an internal thread 131 contained within the piston 130 to permit the plunger rod 138 to be coupled to the syringe 122. The first open end 148 of the housing 142 preferably has a finger flange 168 with a central bore (not shown) to aid in gripping the pharmaceutical transfer assembly 136 during operation.

[0043] The transfer tube / vial socket assembly 139 generally comprises a hollow tube 141 and a vial socket 184. The hollow tube 141 has a first portion 143, and a second portion 145 adjacent the first portion 143. The first portion 143 preferably has a smaller diameter than the second portion 145. The hollow tube 141 has a first end 147, and a second end 151 opposite the first end 147. The first end 147 preferably has a blunt tip, and an aperture 149 adjacent the blunt tip that is in fluid communication with the inside of the hollow tube. The second end 151 has a hollow piercing member 178 with a tip 180. The hollow piercing member 180 may be any suitable device well known in the art, and in one embodiment is a hollow needle such as a standard spike. The vial socket 182 is appropriately sized and shaped to receive a standard pharmaceutical vial 110 having the penetrable closure 116 and the cap 120, described above. Preferably, the vial socket 182 has an inner annular ridge 184 of smaller dimension than the vial socket 182 for

positively engaging the cap 120 of the vial 110 once it is fully inserted into the vial socket (as shown in Figures 23-25).

[0044] The syringe 122 is slightly modified in this aspect of the invention. Namely, the piston 130 has an aperture 153 with a diameter that is slightly smaller than the diameter of the first portion 143 of the hollow tube 141 to allow snug passage of the hollow tube 141 through the piston 130, as will be subsequently described.

[0045] Referring now to Figures 21-26, the successive stages in deployment of the pharmaceutical transfer assembly as shown in Figure 20 to transfer a fluid pharmaceutical component from a prepackaged pharmaceutical vial 110 to a syringe 122 according to a further aspect of the invention are shown.

[0046] Still referring to Figures 21-26, the method for deploying the pharmaceutical transfer assembly 136 is described in detail below. Step (a) involves screwing external thread 166 into the internal thread 131 within piston 130 and screwing external thread 164 part way into the internal thread 162 within the second portion 154 of the housing 142 to create the assembly shown in Figure 21. It is understood that before the fluid transfer occurs, the aperture 149 is wholly contained within the aperture 153 in the piston 131 to create a fluid seal. Step (b) involves removing the cover 120 of the pharmaceutical vial 110 (Figure 22). Step (c) involves inserting and snap fitting the pharmaceutical vial 110 into the vial socket 182 of the transfer tube / vial socket assembly 139 such that the tip 180 of the hollow piercing member 178 penetrates the penetrable closure 116 on the pharmaceutical vial 110 (see Figure 22). Step (d) involves screwing the external thread 164 into the internal thread 162 within the second portion 154 of the housing 142 to advance the blunt tip of the hollow tube 141 longitudinally within the inner sleeve 152 of the housing 142 from the retracted position to the advanced position wherein aperture 149 in the blunt tip of the hollow tube 141 is above piston 130 to create fluid communication between the pharmaceutical vial 110 and the syringe 122 (see Figure 23). Step (e) involves advancing the syringe

body 124 longitudinally towards the pharmaceutical vial 110 to aspirate air into the pharmaceutical vial 10. Step (f) involves inverting the pharmaceutical delivery system 134 to aspirate the fluid pharmaceutical component from the prepackaged pharmaceutical vial 110 into the syringe 122. Step (g) involves unscrewing the external thread 164 from the internal thread within the second portion 154 of the housing 142 to retract the blunt tip of the hollow tub 141 longitudinally within the inner sleeve 152 of the housing 142 from the advanced position to the retracted position wherein the aperture 147 in the blunt tip of the hollow tube is wholly contained within the piston 130 to create a seal (see Figure 26). Once the hollow tube has been retracted, the syringe 122 is ready for use. To use the filled syringe 122 the tip cap 132 is removed and a needle (not shown) attached. The plunger rod 138 forms the plunger to discharge the transferred fluid from the syringe 122.

[0047] Although the invention has been described in the apparatus and methods in terms of transferring a single dose from the vial 110 to the syringe 122, the apparatus and methods described herein can also be used to transfer a plurality of doses from the vial 110 to the syringe 122 while keeping the pharmaceutical delivery system 134 intact thereby maintaining sterility. After the first dose has been administered, the needle (not shown) is removed from the syringe 122, the tip cap 132 is replaced, and the procedure may be repeated for a second or subsequent dose. The amount drawn in for each repeated dose can be controlled by the degree of movement of the piston 130 within the syringe 122.

[0048] Referring now to Figures 27-37, a pharmaceutical delivery system made in accordance with another aspect of the present invention is shown generally at 234. The pharmaceutical delivery system 234 has a syringe 222, a pharmaceutical transfer assembly shown generally at 236, and a pharmaceutical vial 210.

[0049] The pharmaceutical transfer assembly 236 has a piston backstop 201, a detachable needle transfer plunger rod shown generally at 238, and a vial socket assembly shown generally at 240.

[0050] Optionally, a sheath assembly 203 can be secured over the neck end 228 of the syringe 222 for reasons that will be subsequently described. The sheath assembly 203 has a plastic tip cap 205, and a hard body sheath 207.

[0051] Referring now to Figure 27 and 42, the piston backstop 201 can be coupled to a flange 227 of the syringe 222 to facilitate sterilization of the transfer assembly 236, to prevent accidental activation of the pharmaceutical delivery system 238, and to prevent a piston 230 from being accidentally dislodged from the open end 226 of the syringe 222 as will be described in more detail below. The piston backstop 201 has a bottom plate 209 extending radially from a preferably cylindrical collar 213. The bottom plate 209 has an aperture 289, two top plate extensions 211a, 211b, and two side walls 213a, 213b respectively connecting the bottom plate 209 to the two top plate extensions 211a, 211b. In this arrangement, the bottom plate 209, side walls 213a, 213b, and the top plate extensions 211a, 211b form a pair of gaps 287a, 287b which is sized to snugly receive the flange 227 of the syringe 222. Collar 213 has an internal thread 215, and an inner diameter that is slightly larger than the outer diameter of the detachable needle transfer plunger rod 238 to permit the needle transfer plunger rod 238 to move axially within the piston stop 201. The piston backstop 201 may have a pair of snaps 291a, 291b positioned on the two top plate extensions 211a to permit attachment of the sheath 207 as will be subsequently described.

[0052] The piston backstop 201 can be formed in any conventional manner such as injection moulding, and may be made of appropriate plastics, hard rubber materials, or the like. The piston backstop 201 is preferably made from a slightly flexible material to allow it to flex slightly as it is placed about flange 227. Preferably, the piston backstop 201 and preferably the gap is shaped and sized to fit snugly about the flange 227 to ensure that the system does not disassemble during deployment.

[0053] The detachable needle transfer plunger rod 238 may be of any suitable size and shape. In one aspect of the invention, the detachable

needle transfer plunger rod 238 has the same dimensions as a standard detachable plunger rod as is well known by a person skilled in the art. The detachable needle transfer plunger rod 238 has a housing 242, a needle hub assembly 244, and a resilient biasing member 246.

[0054] The housing 242 has a first open end 248, a second open end 250 opposite open end 248, and an inner sleeve 252 disposed between the first and second open ends 248, 250. The inner sleeve 252 is appropriately sized and shaped to receive therein the needle hub assembly 244 and the resilient biasing member 246, which will be described in more detail below. The inner sleeve 252 generally has a first portion 254 and an adjacent second portion 256. The first portion 254 has a larger diameter than the second portion 256, and an inner annular shoulder 258 is formed at the juncture between the first and second portions 254, 256. There is a slot 217 in the first portion 254 of the inner sleeve 252 with a top end 219 and a bottom end 221. A latch 223 adjacent the bottom end 221 of the slot 217 supports the needle hub assembly 244 in a retracted or "inactivated" position while not in use, as will be subsequently described. An external thread 266 on the second portion 256 of the housing 242 matingly cooperates with an internal thread 225 contained within the piston 230 to permit the needle transfer plunger rod 238 to be threadedly coupled to the piston 230. There is an external thread 235 on the first portion 254 of the housing 242 that matingly cooperates with the internal thread 215 in the piston backstop 201 to permit longitudinal movement of the needle transfer plunger rod 238 relative to the piston backstop 201. The first open end 248 of the housing 242 preferably has a finger flange 268 with a central bore to aid in gripping the pharmaceutical transfer assembly 236 during operation.

[0055] The needle hub assembly 244 has a first hollow piercing member 270 having a tip 272 coupled to a needle hub 274. The first hollow piercing member 270 may be any suitable device known in the art, and in one embodiment is a hollow needle such as a standard cannula. The needle hub assembly 244 has a size and shape to permit longitudinal movement within

the inner sleeve 252 between a retracted or "unactivated" position (as seen in Figures 29-30, 32-33, and 37) and an advanced or "activated" position (as seen in Figures 31, 34-36). As will be described more particularly below, in the retracted position, the tip 272 of the first hollow piercing member 270 is fully contained within the second portion 256 of the inner sleeve 252 of the housing 242. In the advanced position, the tip 272 of the first hollow piercing member 270 protrudes past the second portion 256 of the inner sleeve 252 of the housing 242 and penetrates completely through the piston 230. The needle hub 274 has a flange 279 having a bottom surface 231 which abuts a top surface 233 of the latch 223 to support the needle hub assembly 244 within the housing 242 while in the retracted or "inactivated" position. The needle hub 274 has a female luer slip 500 fitting to permit receipt of a post 276 of the vial socket assembly 240. The needle hub 274 and the post 276 act to hold the vial socket assembly 240 to the needle transfer plunger rod 238 initially when the needle hub assembly 244 is in the retracted or "inactivated" position.

[0056] The resilient biasing member 246 may be any suitable device known in the art, and in one embodiment is a compressible spring. The resilient biasing member 246 is sized and shaped to fit within the first portion 254 of the inner sleeve 252 between the surface 502 of the needle hub 274 and the shoulder 258. While the needle hub assembly 244 is in the retracted or "unactivated" position, the resilient biasing member 246 is at rest (e.g. no force is being applied to or by the resilient biasing member 246 by the hub 274). While the needle hub assembly 244 is in the advanced or "activated" position, the resilient biasing member 246 is compressed against the annular shoulder 258 by the hub 274 (e.g., a force is being applied to the resilient biasing member 246). A main purpose of the resilient biasing member 246 is to retract the needle hub assembly 244 to the retracted or "unactivated" position after the fluid transfer has been completed and the vial socket assembly 240 has been removed from the needle transfer plunger rod 238, as will subsequently be described.

[0057] The vial socket assembly 240 has a post 276, a collar 237, an annular recess 239 having an internal thread 241, a second hollow piercing member 278 having a tip 280, and a vial socket 282. The post 276 has a male luer slip fitting that permits coupling between the post 276 and the female luer slip fitting 502 on the needle hub 274 while the pharmaceutical transfer assembly 236 is in the retracted or "inactivated position". The flange 268 matingly cooperates the internal thread 241 in the annular recess 239 to securely couple the vial socket assembly 240 to the needle transfer plunger rod 238. The second hollow piercing member 278 may be any suitable device known in the art, and in one embodiment is a hollow needle such as a spike. The vial socket 282 is appropriately sized and shaped to receive a standard pharmaceutical vial having the penetrable closure and the cap, described above. Preferably, the vial socket 282 has a plurality of latches 243 (in the form of an annular ridge around the inner circumference of the vial socket 240, which is divided by a plurality of longitudinal slots 245). The slots 245 permit the vial socket 240 some flexibility to facilitate insertion of the pharmaceutical vial 210. The latches 243 positively retain the cap 220 of the vial 210 once it is fully inserted into the vial socket 240 (as shown in Figures 30-31, and 34-36).

[0058] The optional sheath assembly 203 generally comprises a plastic cap 205 having an internal thread 505, and a hard body sheath 207 having a corresponding external thread 293 and an annular detent 295. The annular detent 295 snap fits into the snaps 291a, 291b on the top plate extensions of the piston backstop 201 to positively retain the sheath 207 on the piston backstop 201. The sheath assembly 203 protects the syringe 222 from breakage, and also prevents a rubber tip cap 232 from dislodging from the neck end 228 of the syringe 222 during both transport and deployment of the pharmaceutical transfer system 234.

[0059] Referring now to Figure 29 and 32, the pharmaceutical transfer assembly of Figures 27-28 is shown generally at 236 with the needle transfer assembly 244 in a retracted position and the transfer needle plunger rod 238

in a first position. While in this configuration, the external thread 235 of the housing 242 is engaged with the internal thread 215 of the piston backstop 201. Additionally, the second portion 256 of the housing 242 is contained within the collar 213 of the piston backstop 201 and does not extend into the open end 226 of the syringe 222. This configuration has a number of advantages including that it permits sterilizing gas to pass through the gap 285 created between the second portion 256 of the housing 242 and the internal thread 235 of the piston 230, prevents accidental activation of the system since the needle transfer plunger rod 238 must be rotated to fully disengage the external thread 235 from the internal thread 215 of the piston stop 201 before the external thread 266 of needle transfer plunger rod can be threaded into the internal thread 225 of the piston 230, and permits the flange 227 of the syringe 222 to be inserted into the piston backstop 201 with ease during manufacture since the flange 227 of the syringe 222 can rotate freely within the piston backstop 201 without interference from the needle transfer plunger rod 238.

[0060] Figure 30 is a cross-sectional view of the pharmaceutical transfer assembly 236 with the needle hub assembly 244 in a retracted position and the needle transfer plunger rod 238 in a second position. While in this configuration, the external thread 235 of the housing 242 is fully disengaged from the internal thread 215 of the piston backstop 201. The second portion 256 of the housing 242 extends past the collar 213 of the piston stop 201 into the open end 226 of the syringe 222, and the external thread 266 of the housing 242 is engaged with the internal thread 225 in the piston 230. While in this configuration, the pharmaceutical transfer assembly is ready to be deployed. The piston 230 cannot be accidentally removed from the open end of the 226 of the syringe 222 by accidentally pulling on the vial, because a stop is created when the external thread 235 on the housing 242 abuts the internal thread 215 on the piston backstop 201.

[0061] Referring now to Figures 31 and 34, the pharmaceutical transfer assembly 236 is shown with the needle hub assembly 244 in an advanced

position and the needle transfer plunger rod 238 in a second position. The second portion 256 of the housing 242 extends past the collar 213 of the piston stop 201 into the open end 226 of the syringe 222, and the external thread 266 of the housing 242 is engaged with the internal thread 225 in the piston 230. While in this configuration, the flange 268 of the housing 242 is matingly engaged with the internal thread 241 positioned in the annular recess 239 of the collar 237. This creates fluid communication between the syringe 222 and the vial 210 when the vial 210 is inserted into the vial socket 240.

[0062] Figures 32-37 show the successive stages in the deployment of a pharmaceutical transfer assembly 236 shown in Figure 27 to reconstitute a first fluid pharmaceutical component from a pre-filled syringe 222 with a second pharmaceutical component from a pharmaceutical vial 210. The second pharmaceutical component contained within the pharmaceutical vial 210 may be either a fluid or a solid (e.g. lyophilized powder).

[0063] Still referring to Figures 32-37, the method for deploying the pharmaceutical transfer assembly 236 is described in detail below. First, in step (a) the user threads the external thread 235 on the needle transfer plunger rod 238 into the internal thread 215 within the piston backstop 201. Then the user inserts to the post 276 of the vial socket assembly 240 into the needle hub 274 to create the assembly shown in Figures 29 and 32. Next, in step (b) the user removes the cover 220 of the pharmaceutical vial 210 (see Figure 33). Then, in step (c) the user inserts and snap fits the pharmaceutical vial 210 into the vial socket 282 of the vial socket assembly 240 such that the tip 280 of the second hollow piercing member 278 penetrates the penetrable closure 216 on the pharmaceutical vial 210 (see Figure 33). It is understood that the two procedures of step (a) can be performed first followed by steps (b) and (c) in that order, or steps (b) and (c) can be performed first in that order followed by step (a). After completing steps (a), (b), and (c), in step (d) the user threads the needle transfer plunger rod 238 so that the external thread 235 on the housing 242 becomes fully disengaged from the internal

thread 215 on the piston backstop 201 and the external thread 266 matingly engages the internal thread on the piston 230 (see Figure 30). Next, in step (e) the user advances both the pharmaceutical vial 210 and the vial socket assembly 240 forward toward on the syringe 222 and couples the vial socket assembly 240 into place by threading the flange 268 of the housing 242 into the internal thread 241 positioned in the annular recess 239 of the collar 237 of the vial socket 240. This, in turn, advances the tip 272 of the first hollow piercing member longitudinally within the inner sleeve 252 of the housing 242 from the retracted position to the advanced position wherein the tip 272 of the first hollow piercing member 270 penetrates completely through the piston 230 into the body of the syringe 222. With both tip 272 and tip 280 having pierced their respective items, this creates fluid communication between the pharmaceutical vial 210 and the syringe 222 (see Figures 31 and 34). Next in step (f) the user advances the vial 210 longitudinally towards the syringe 222. This moves the piston 230 within the syringe 222 forcing the fluid within the syringe body 224 into and through the needle assembly 244 and through the vial socket assembly 240 to inject the first fluid pharmaceutical component into the pharmaceutical vial 210 (see Figure 35). Then, in step (g) the user swirls the pharmaceutical delivery system 234 to dissolve, dilute or suspend the first fluid pharmaceutical component into the second pharmaceutical component. Next in step (h), the user inverts the pharmaceutical delivery system 234 and withdraws the vial 210 longitudinally away from the syringe 222 to aspirate the now mixed contents of the pharmaceutical vial 210 into the syringe 222 (see Figure 36). The piston 230 cannot be accidentally removed from the open end of the 226 of the syringe 222 during this step by merely withdrawing the vial away from the syringe, because a stop is created when the external thread 235 on the housing 242 abuts the internal thread 215 on the piston backstop 201. In step (i), the user detaches the vial socket assembly 240 from the needle transfer plunger rod 238 (by unthreading the two and pulling the post 276 of the vial socket assembly 240 out of the needle hub 274) to provide a filled syringe 222 ready for use (see Figure 37). To use the filled syringe, the user removes the tip cap 232 and attaches a needle (not

shown). The needle transfer plunger rod 238 forms the plunger to discharge the mixed pharmaceutical from the syringe 222 through the attached needle.

[0064] It will be understood by a person skilled in the art that once the user detaches the vial socket assembly 240 from the needle transfer plunger rod 238 (by unthreading the two), the resilient biasing member 246 retracts the first hollow piercing member back to the retracted or "inactivated" position. As such, the piston 230 reseals to prevent fluid communication between the syringe 222 and the needle transfer plunger rod 238. Accordingly, when the user uses syringe 222 to deliver the reconstituted multi-component pharmaceutical to a patient or iv line, the user simply depresses the needle transfer plunger rod 238 in a conventional manner.

[0065] Figure 42 shows another embodiment of a piston backstop 301 according to the present invention. The piston backstop 301 has a bottom plate 309 with an aperture 389, two top plate extensions 311a, 311b, and two side walls 313a, 313b connecting the bottom plate 309 to the two top plate extensions 311a, 311b. In this arrangement, the bottom plate 309, side walls 313a, 313b, and the top plate extensions 311a, 311b form a pair of gaps 387a, 387b which is sized to snugly receive the flange 227 of the syringe 222. An inner surface defining the aperture 389 has an internal thread 315, and an inner diameter that is slightly larger than the outer diameter of the detachable needle transfer plunger rod 238 to permit the needle transfer plunger rod to move axially within the piston stop 301. The piston backstop 301 may have a pair of snaps 391a, 391b positioned on the two top plate extensions 311a, 311b to permit attachment of the sheath 207. The primary difference between the piston backstop shown in Figure 42 and the one previously described in Figure 41 is that the internal thread 315 is located in the inner surface defining the aperture 389, whereas in the previously described embodiment the internal thread 215 is located in the collar 213.

[0066] Figures 38-40 show the piston backstop 201 being used with a pre-filled syringe 222 having a slightly modified plunger rod 238a according to a further aspect of the present invention. Plunger rod 238a is a conventional

plunger rod having an external thread 235 that is shaped and sized to matingly cooperate with the internal thread 215 of the piston backstop 201. In a similar manner, the piston backstop 201 can be coupled to a flange 227 of the pre-filled syringe 222 to facilitate sterilization of the pre-filled syringe 222, to prevent accidental activation of the pre-filled syringe 222, and to prevent a piston 230 from being accidentally dislodged from the open end 226 of the syringe 222.

[0067] Figure 39 shows a pre-filled syringe 222 ready to be sterilized. While in this configuration, the external thread 235 of the plunger rod 238a is engaged with the internal thread 215 of the piston backstop 201. Additionally, the plunger rod 238a is contained within the collar 213 of the piston backstop 201 and does not extend into the open end 226 of the syringe 222. This configuration has a number of advantages including that it permits sterilizing gas to pass through the gap 285 created between the plunger rod 238a and the internal thread 235 of the piston 230, prevents accidental activation of the prefilled syringe 222, and permits the flange 227 of the syringe 222 to be inserted into the piston backstop 201 with ease during manufacture.

[0068] Figure 40 shows a pre-filled syringe ready to be deployed. While in this configuration, the external thread 235 of the plunger rod 238a is disengaged from the internal thread 215 of the piston backstop 201. The plunger rod 238a extends past the collar 213 of the piston stop 201 into the open end 226 of the syringe 222, and the external thread 266 of the housing 242 is engaged with the internal thread 225 in the piston 230. The piston 230 cannot be accidentally removed from the open end of the 226 of the syringe 222 by accidentally pulling on the plunger rod 238a, because a stop is created when the external thread 235 on the plunger rod 238a abuts the internal thread 215 on the piston backstop 201.

[0069] While the above description constitutes the preferred embodiments, it will be appreciated that the present invention is susceptible to modification and change without departing from the fair meaning of the proper scope of the accompanying claims.

CLAIMS:

1. A transfer assembly for transferring a fluid between a syringe having a slidable piston and a vial having a penetrable seal, the transfer assembly comprising:

a) a housing having a first open end adapted to be releasably coupled to the slidable piston, a second open end opposite the first open end, and a sleeve extending between the first and second open ends, the sleeve having a first portion and a second portion adjacent the first portion, a shoulder being formed between the first and second portions;

b) a needle hub assembly having a first hollow piercing member fluidly connected to a hub, the first, hollow piercing member having a tip with an opening, the needle hub assembly being moveable longitudinally within the sleeve of the housing between a retracted position where the tip of the first hollow piercing member is contained substantially within the sleeve and an advanced position where the first hollow piercing member extends past the sleeve, the hub having a female luer slip at one end, the female luer slip, the hub and the first hollow piercing member being fluidly connected;

c) a vial socket assembly adapted to receive and retain therein a pharmaceutical vial, the vial socket assembly having a male slip luer adapted to be releasably received in the female slip luer on the hub, a second hollow piercing member in fluid communication with the male slip luer, an annular wall surrounding the second hollow piercing member creating a socket into which a pharmaceutical vial can be inserted, the second hollow piercing member extending into the socket, and a plurality of annular ridges spaced about the interior of the annular wall to retain a pharmaceutical vial when inserted into the socket;

d) whereby coupling the vial socket assembly to the first portion of the sleeve of the housing advances the needle hub assembly axially of the housing from the retracted position to the advanced position.

2. A piston backstop for use with a syringe having a body with an open end, a slidable piston positioned within the body, a flange adjacent the open end, and a plunger rod with an external thread to be received in the open end, the piston backstop comprising:

a) a bottom plate having an outer surface and an inner surface, the inner surface defining an aperture;

b) a pair of opposing top plate extensions, each having an outer surface;

c) a pair of side walls connecting portions of the outer surface of the bottom plate to the outer surface of the top plate extensions thereby creating a pair of gaps between the bottom plate and the respective top plate extensions to capture the flange of the syringe therein;

d) the top plate extensions defining a plane, the plane having a gap between the top plate extensions over the axis defined by the aperture to permit passage of the plunger rod therethrough; and

e) a collar extending from the aperture in the bottom plate, the collar having an internal thread that matingly cooperates with the external thread on the plunger rod.

ABSTRACT OF THE DISCLOSURE

The present invention generally relates to pharmaceutical delivery systems, and to methods for using same. More specifically, it relates to an assembly for transferring one or more components of a pharmaceutical composition from a pharmaceutical vial to a syringe or vice versa.

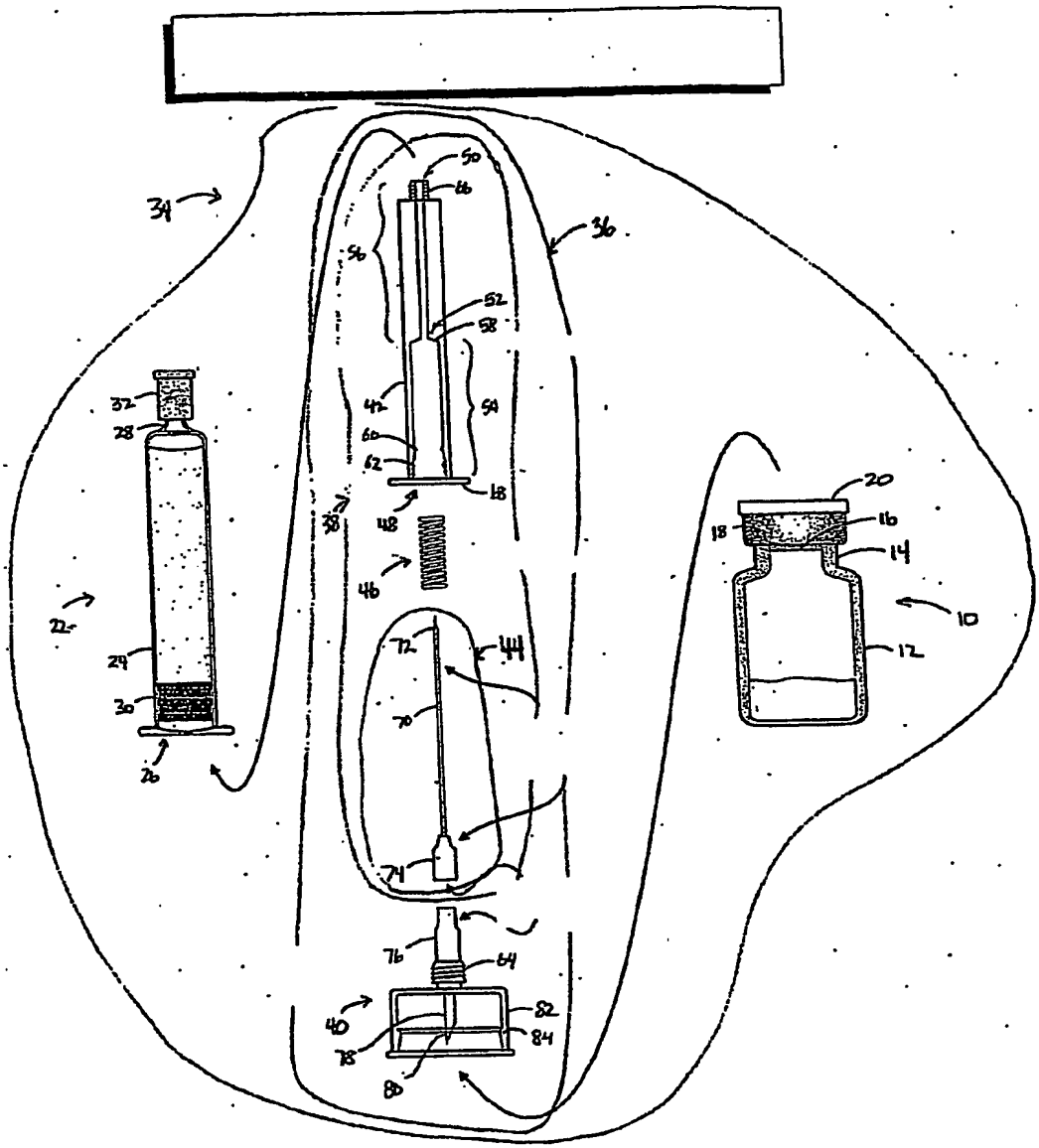

FIGURE 1

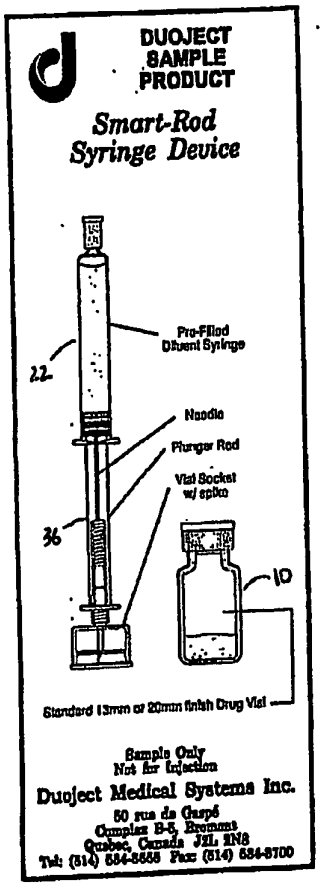

FIGURE 2

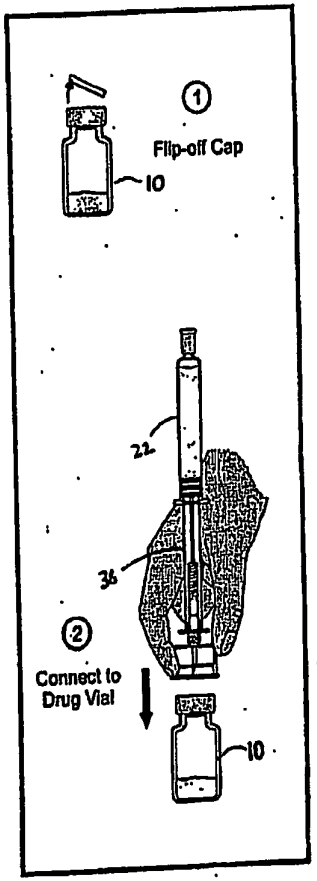

FIGURE 3

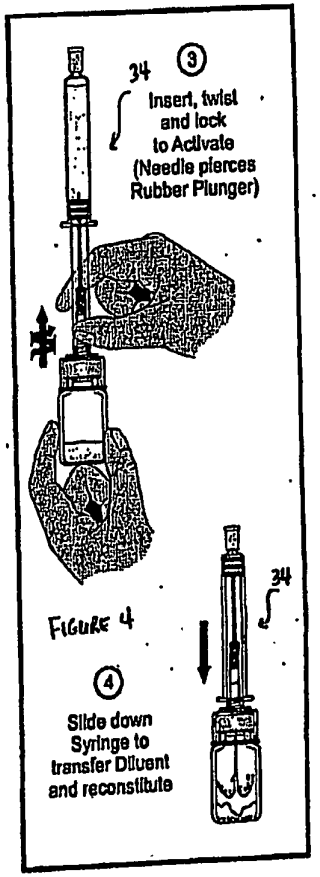

FIGURE 4

FIGURE 5

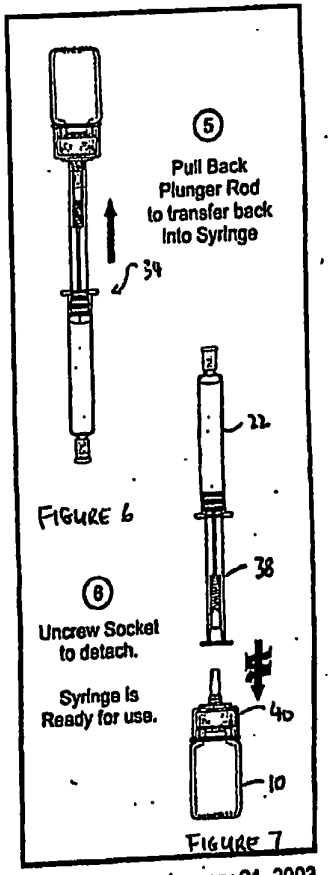

FIGURE 6

FIGURE 7

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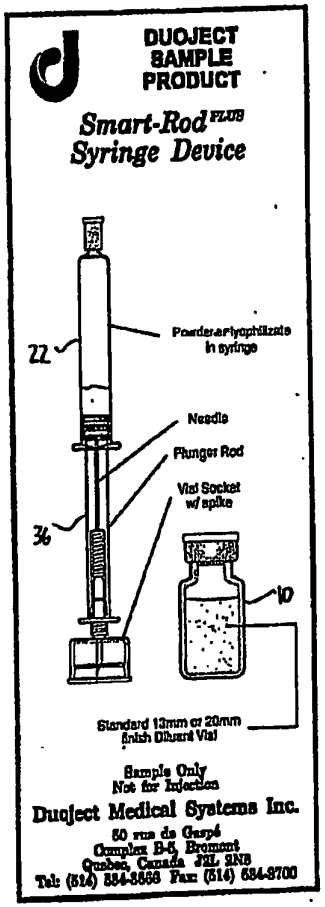

FIGURE 8

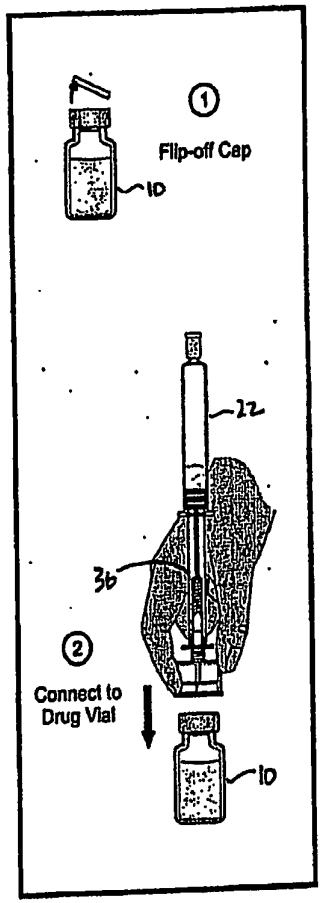

FIGURE 9

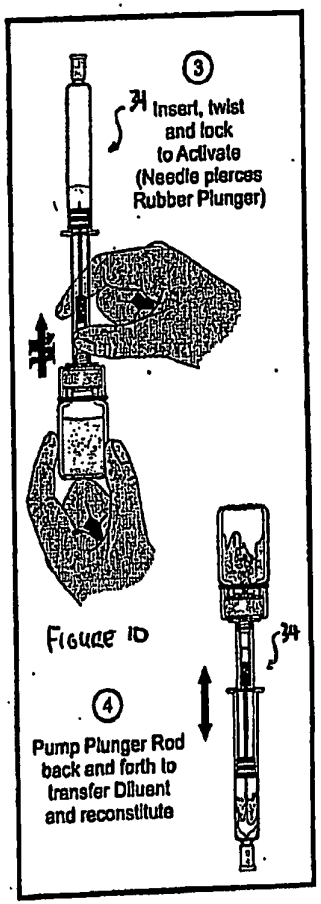

FIGURE 10

FIGURE 11

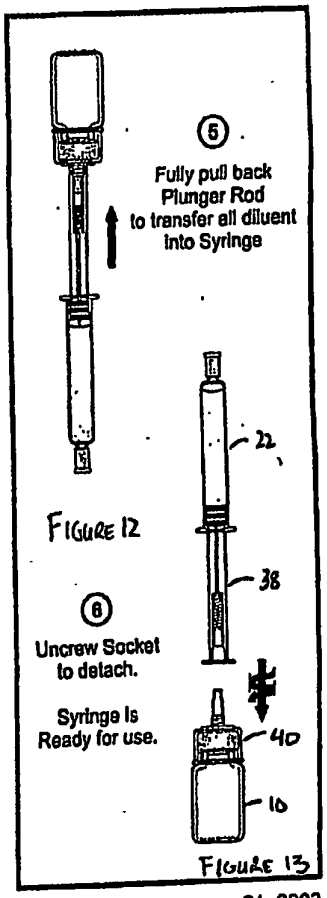

FIGURE 12

FIGURE 13

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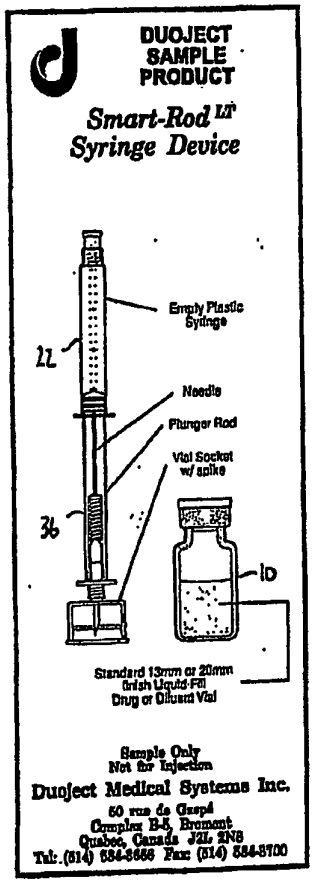

FIGURE 14

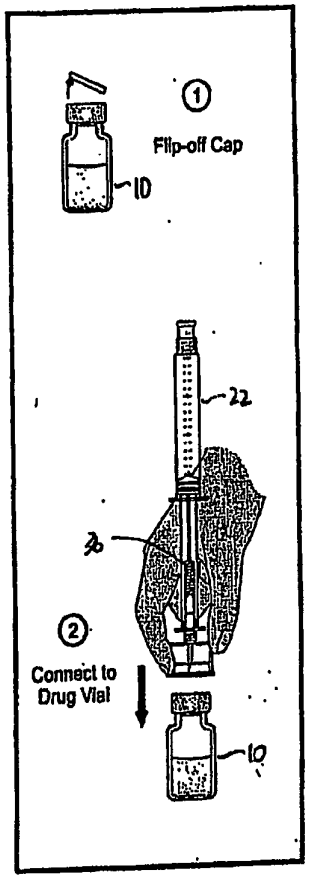

FIGURE 15

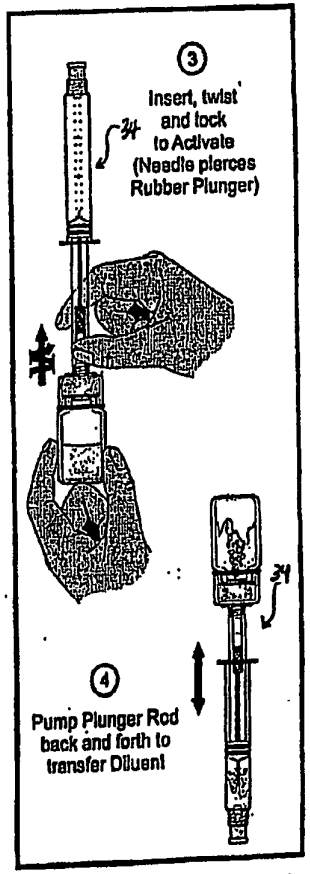

FIGURE 16

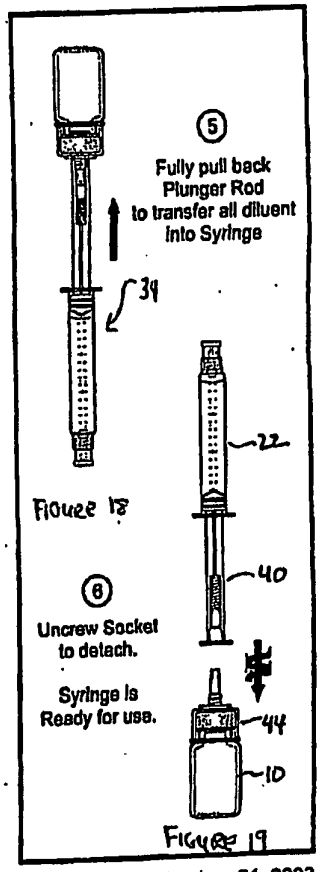

FIGURE 17

FIGURE 18

FIGURE 19

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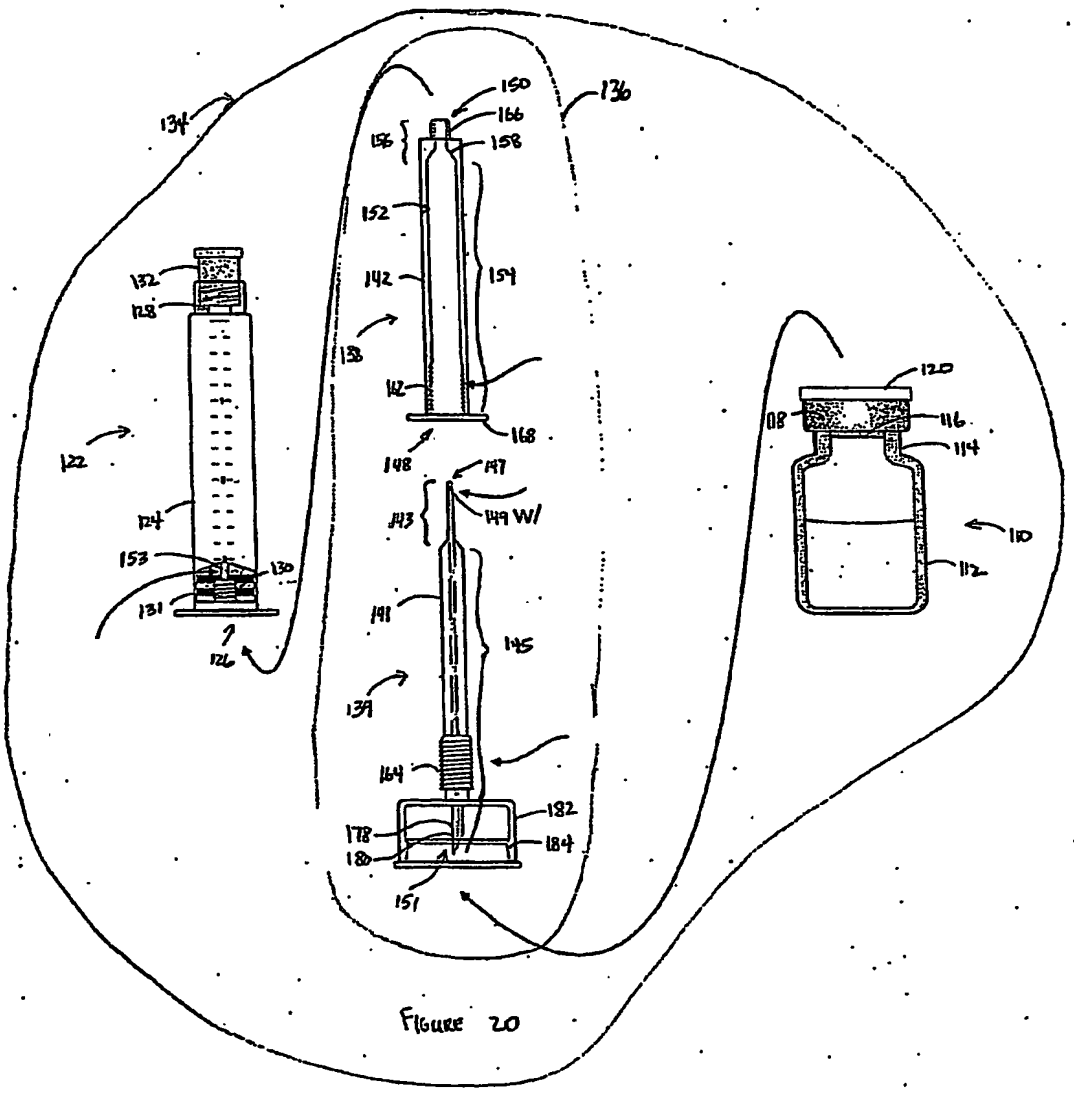

Figure 20

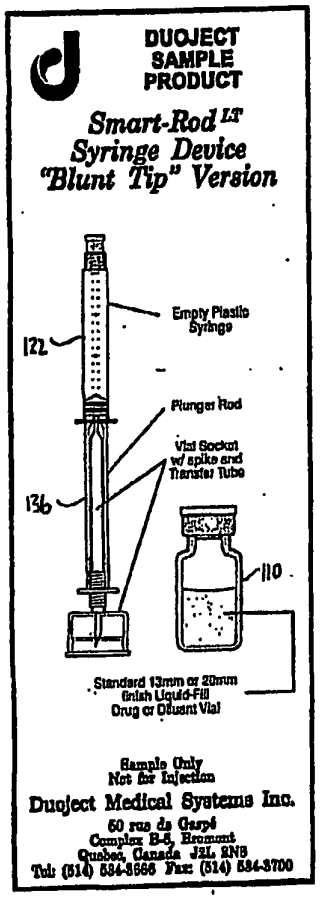

FIGURE 21

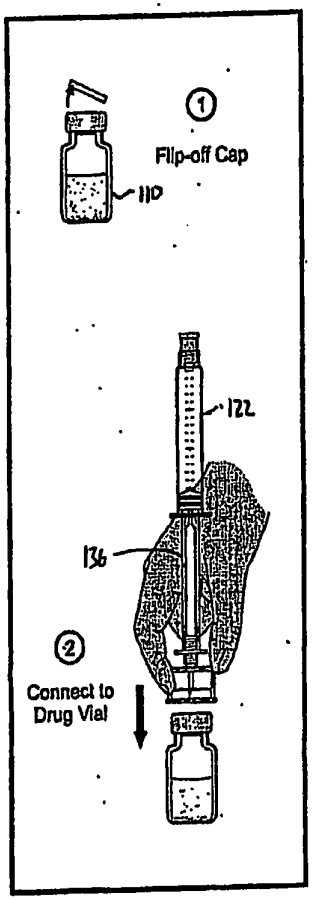

FIGURE 22

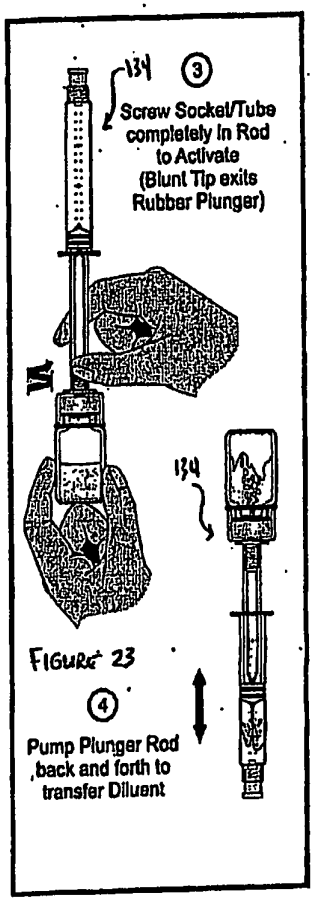

FIGURE 23

FIGURE 24

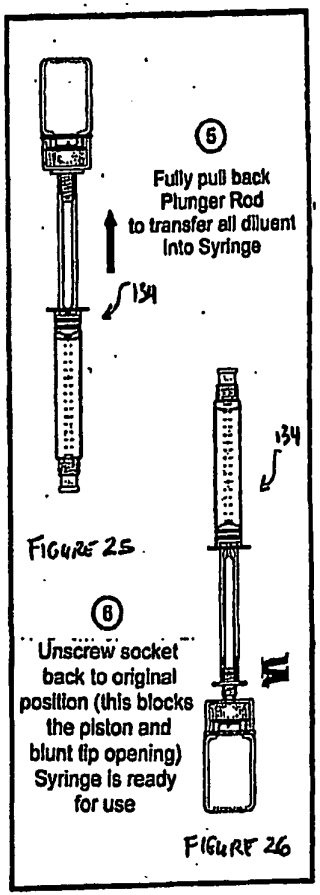

FIGURE 25

FIGURE 26

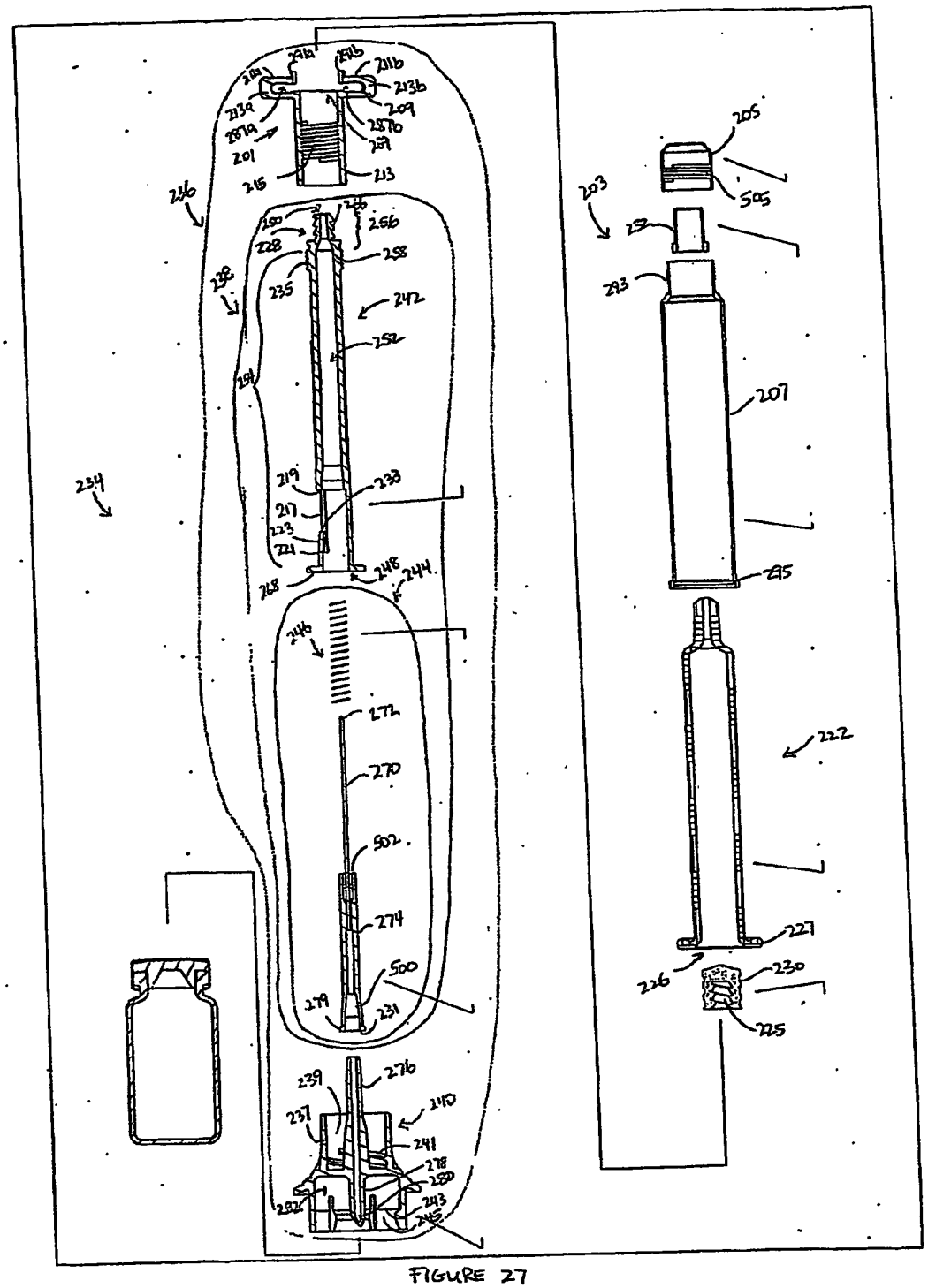

FIGURE 27

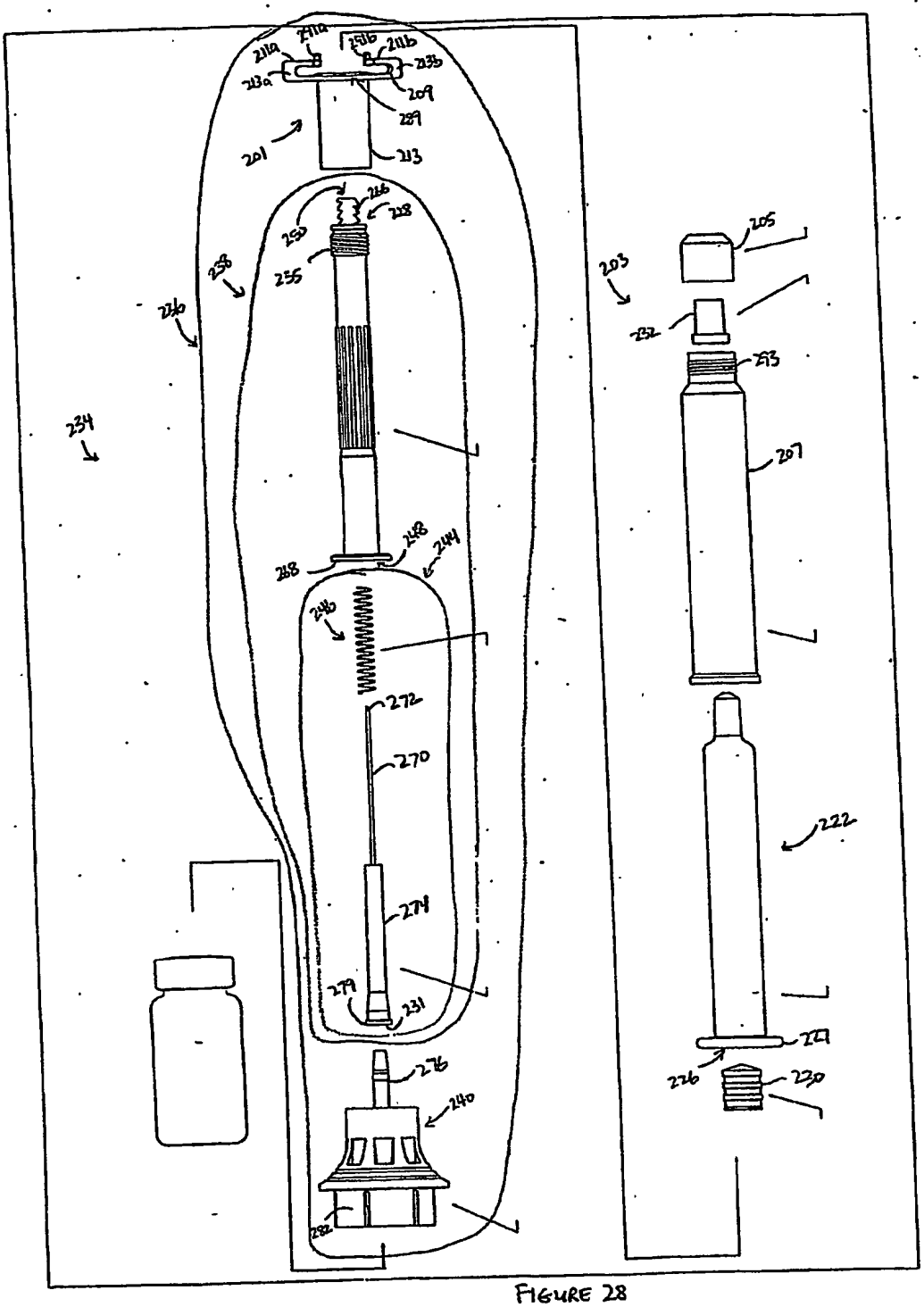

FIGURE 28

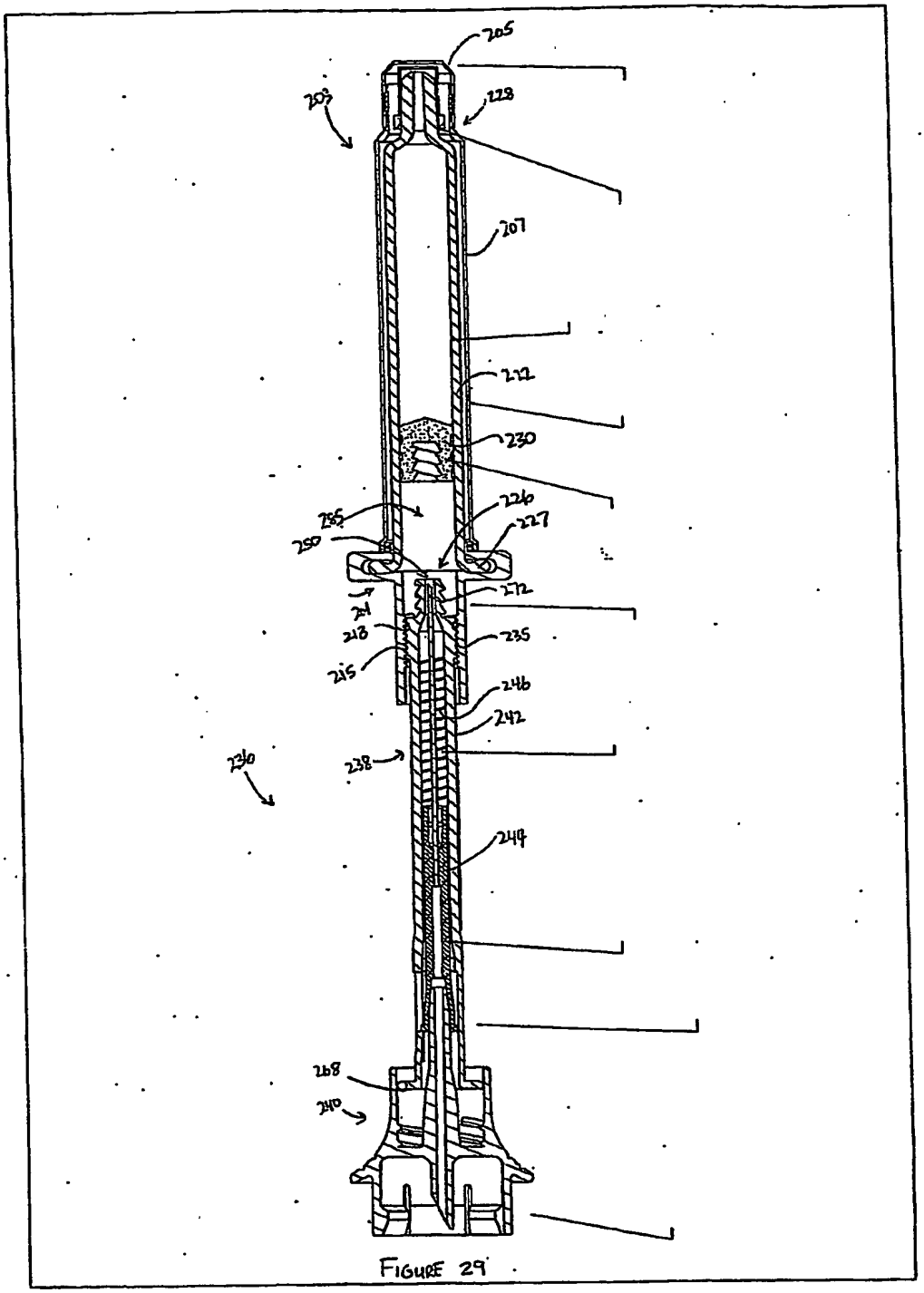

FIGURE 29

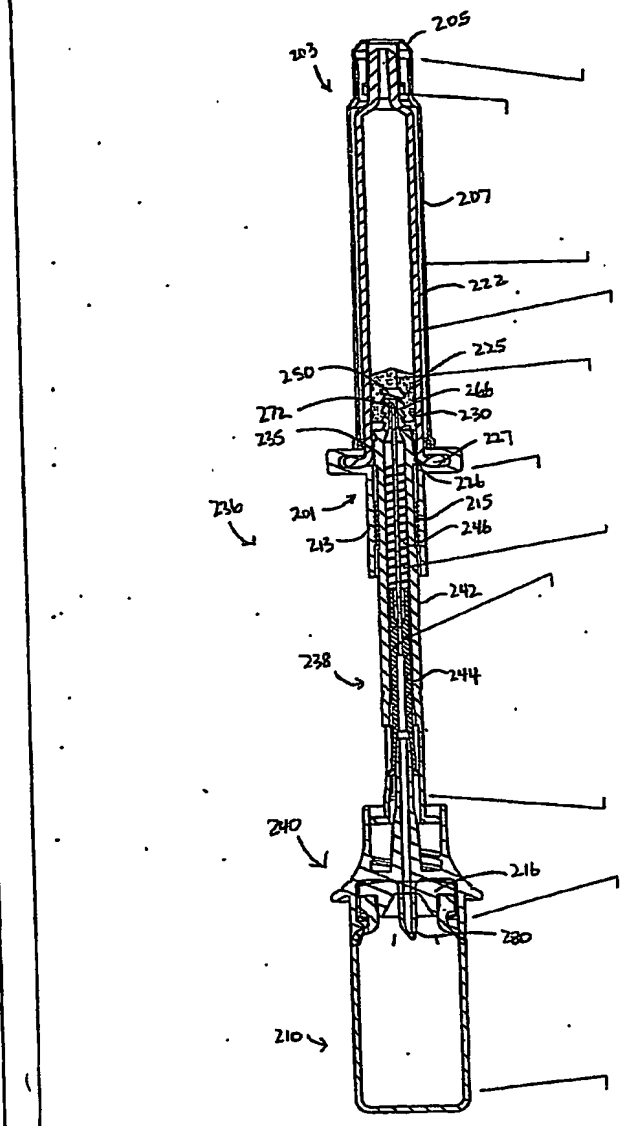

FIGURE 30

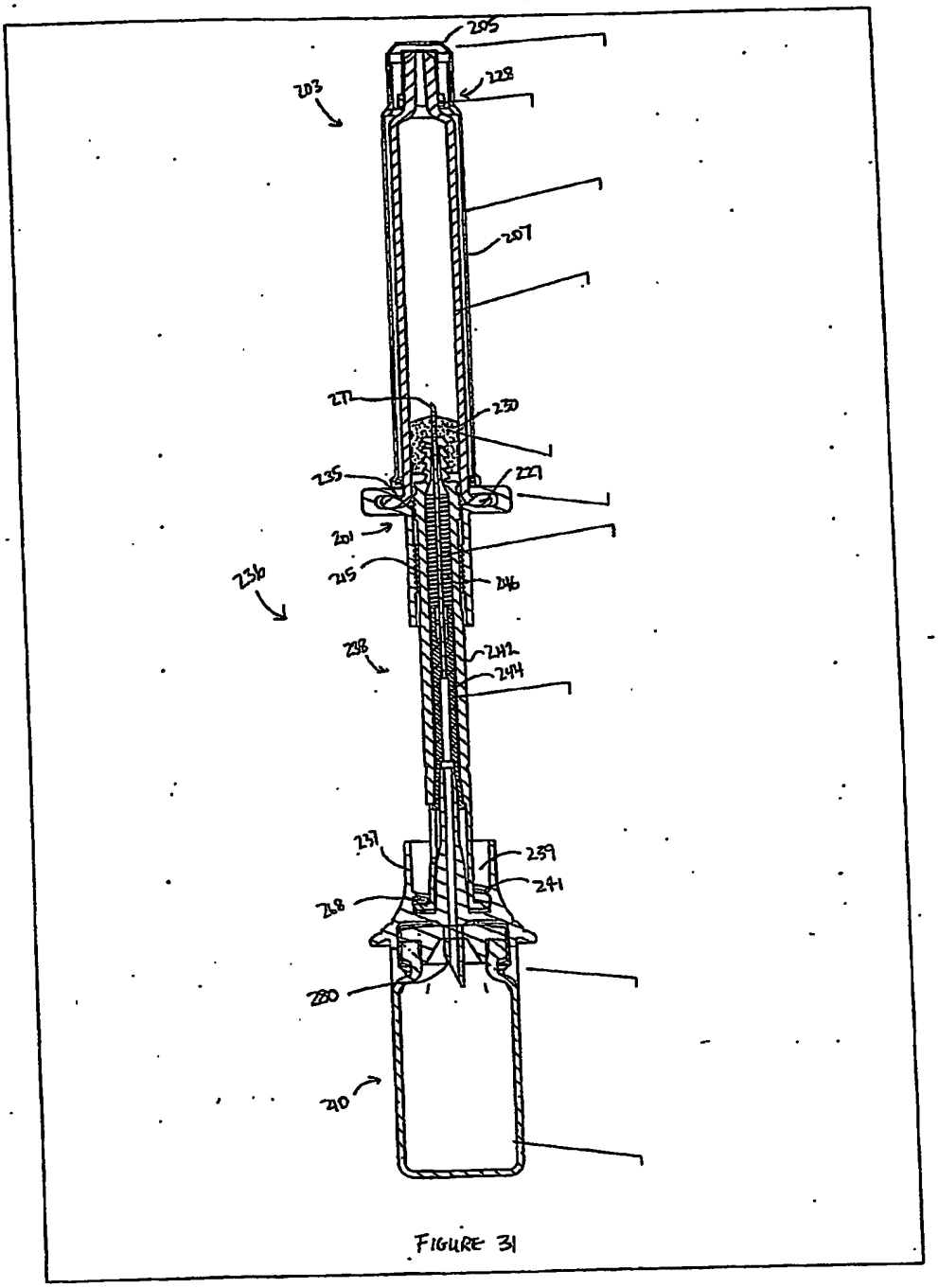

FIGURE 31

Duoject *Smart-Rod*™
Sequence of Operation

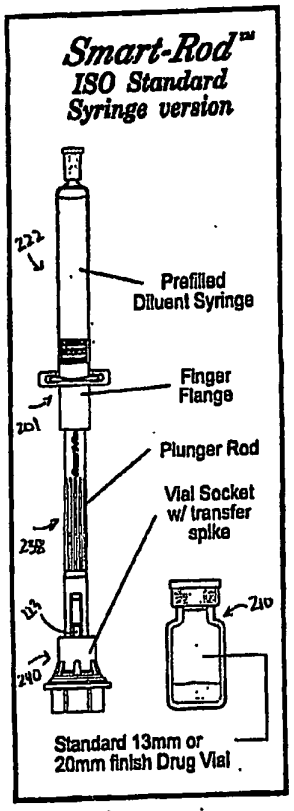

FIGURE 32

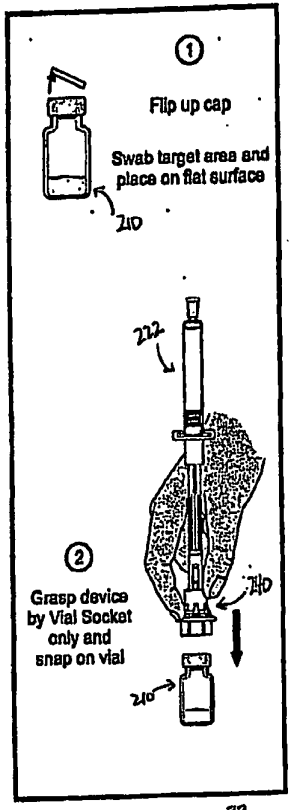

FIGURE 33

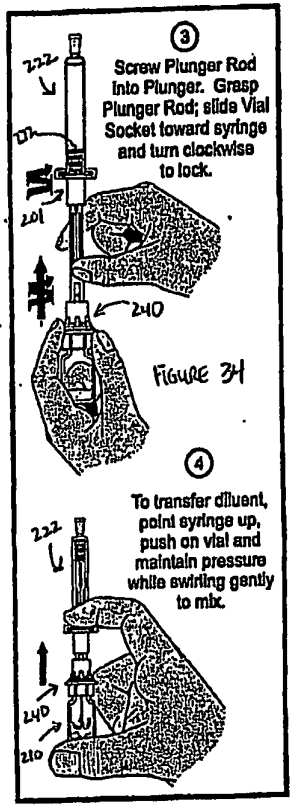

FIGURE 35

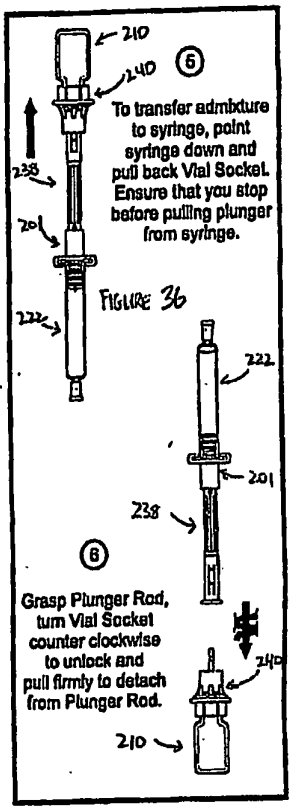

FIGURE 37

DUOJECT MEDICAL SYSTEMS INC

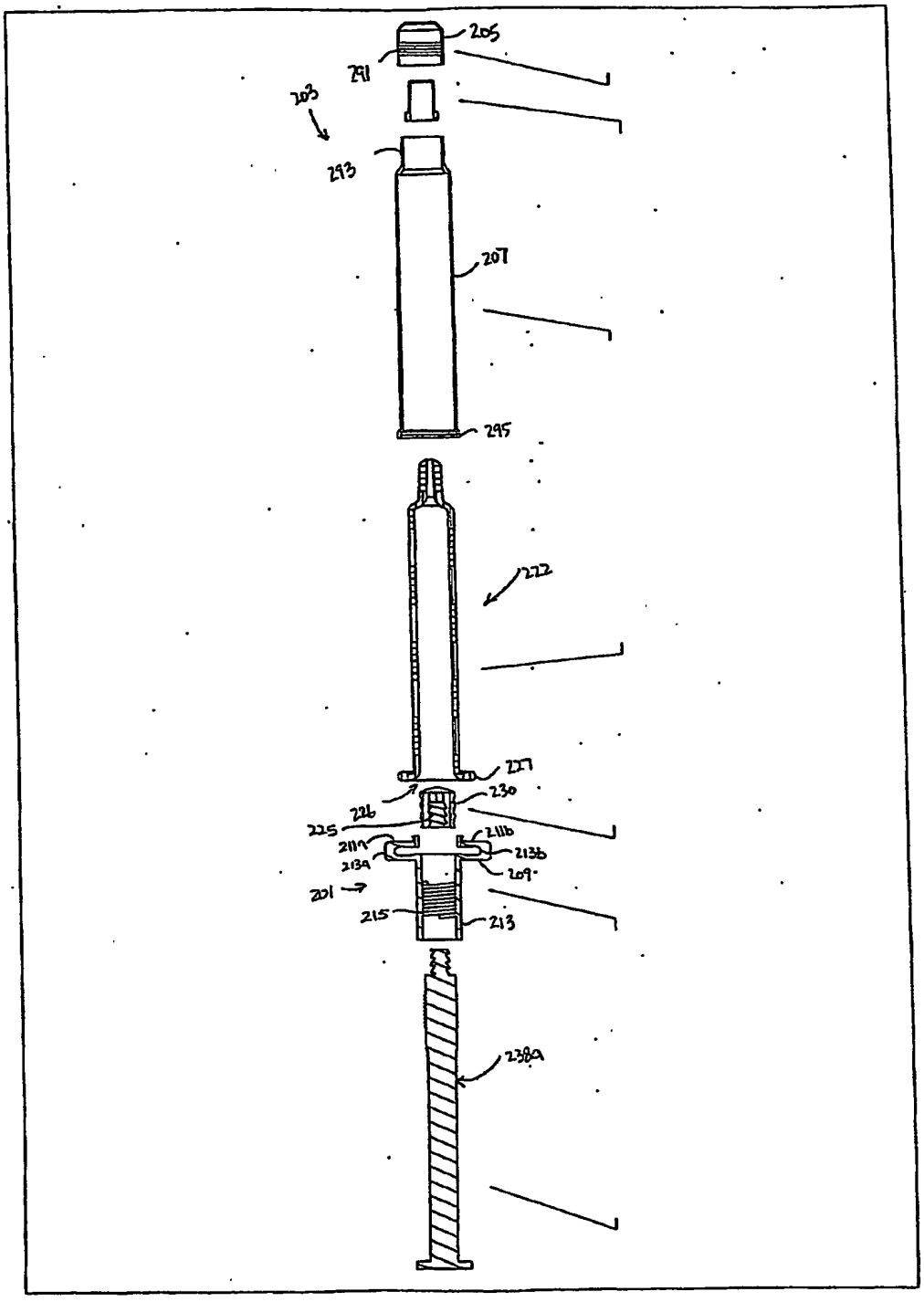

FIGURE 38

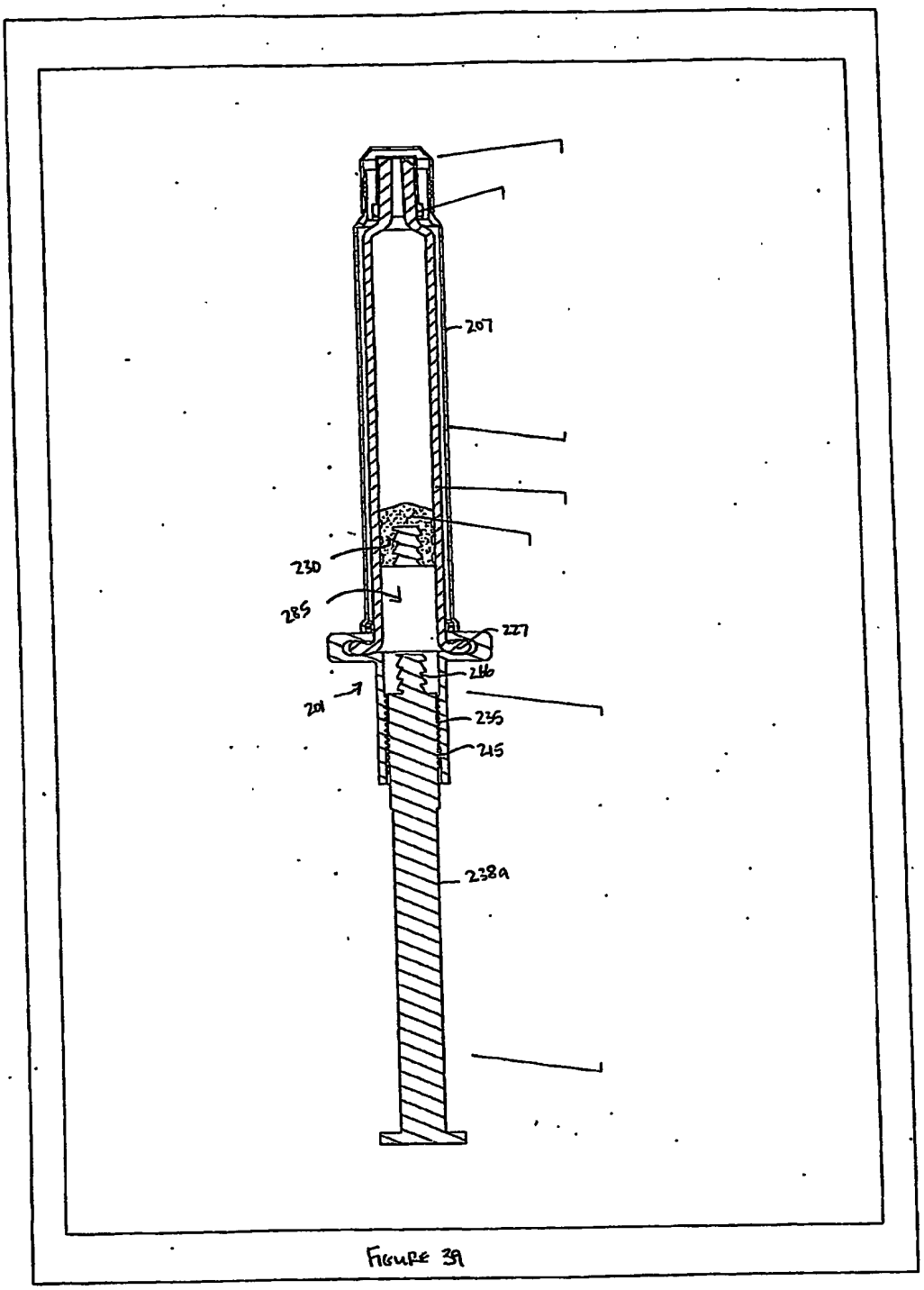

Figure 39

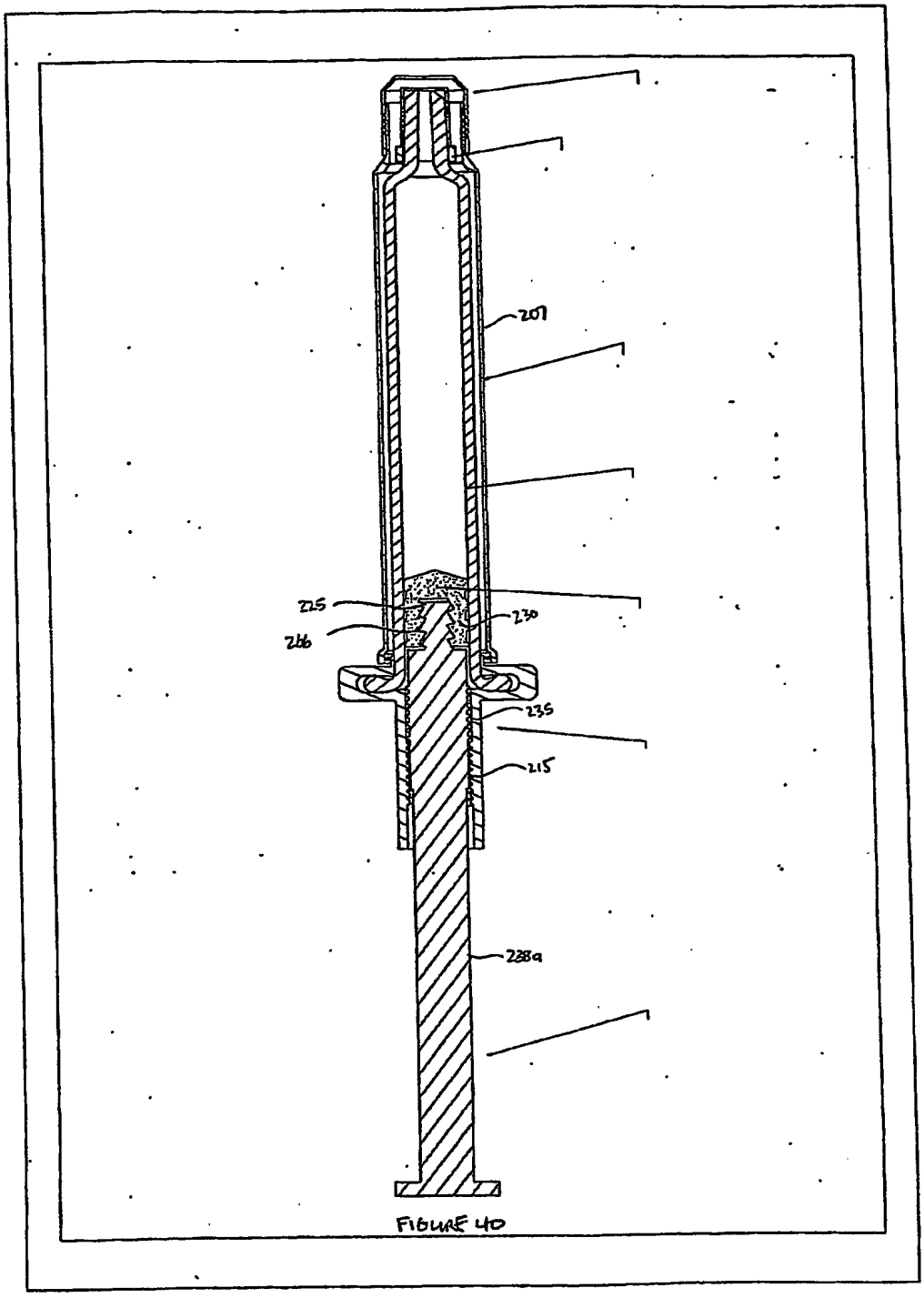

FIGURE 4D

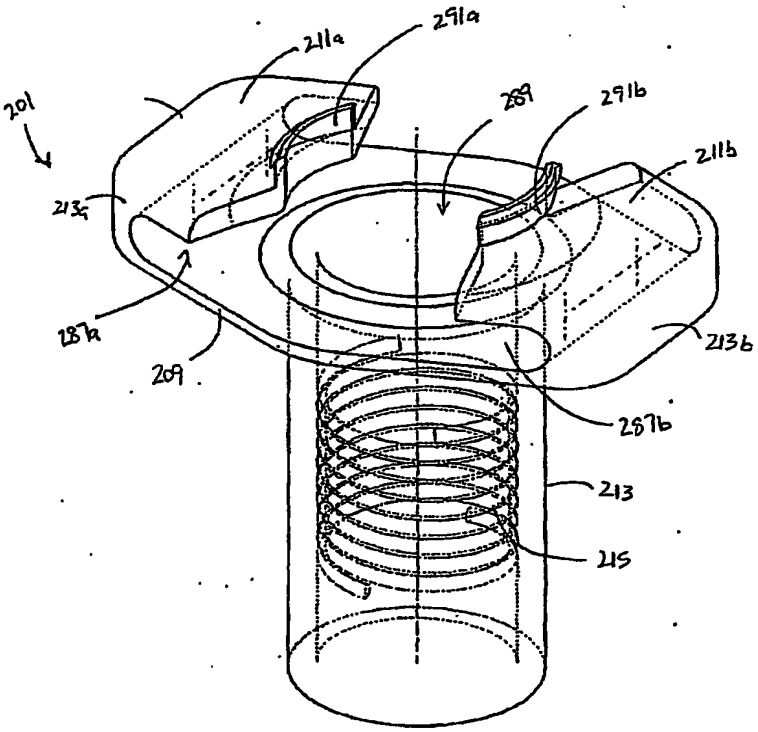

FIGURE 41

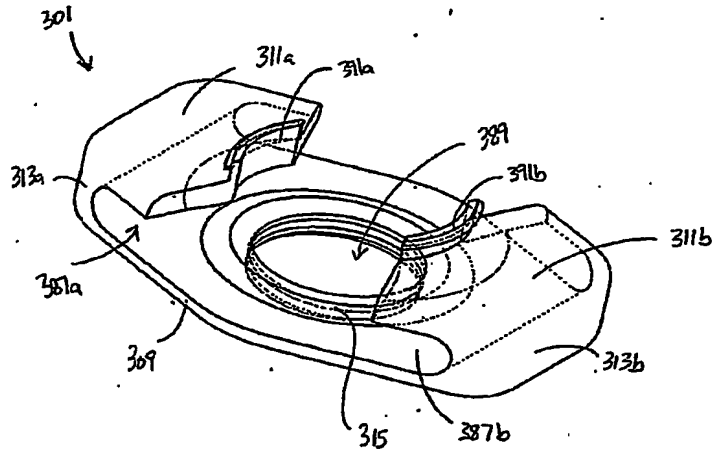

FIGURE 42

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